

# PSJ3

## Exhibit 525

**From:** Rosen, Burt  
**To:** Landau, Dr. Craig; Santopolo, Anthony; Steiner, LaDonna; Stewart, John H. (US); Haddox, Dr. J. David; Heins, James; Must, Alan; Strassburger, Philip; Abrams, Robin; Silbert, Richard W; Udell, Howard (Consultant)  
**CC:** Gasdia, Russell; Seid, Stephen; Innaurato, Mike  
**BCC:** Dr.Craig.Landau@pharma.com; Anthony.Santopolo@pharma.com; LaDonna.Steiner@pharma.com; John.H.Stewart@pharma.com; Dr.J.David.Haddox@pharma.com; james.heins@pharma.com; Alan.Must@pharma.com; philip.strassburger@pharma.com; robin.abrams@pharma.com; RichardW.Silbert@pharma.com; Russell.Gasdia@pharma.com; Stephen.Seid@pharma.com; Stewart, John H. (US)  
**Sent:** 2/24/2009 8:18:14 AM  
**Subject:** FW: REMS Task Force Meeting February 24th  
**Attachments:** csaves.remsv5.pdf

**Here is another model from HDMA, wholesalers.**

**Burt Rosen**  
**VP Federal Government Affairs**  
**700 13th St. NW**  
**Suite 525**  
**Washington, DC 20005**  
**Office: 202-508-0750**  
**Cell:** [REDACTED]

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**From:** Ducca, Anita [mailto:aducca@hdmanet.org]  
**Sent:** Tuesday, February 24, 2009 8:07 AM  
**To:** wrowe@painfoundation.org; Rosen, Burt  
**Subject:** Fw: REMS Task Force Meeting February 24th

Dear Will and Burt,

I will be at another off site meeting first thing this morning and won't be able to print out this attachment. Will you have copies at the PCF meeting availableam. Many thanks, Anita

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**From:** Stephen Porada  
**To:** Will Rowe ; Ducca, Anita; gwt@u.washington.edu ; Michna, Edward,M.D. ; cmonaco@osteopathic.org ; Justine Coffey ; judi.buckalew@ppsv.com ; Steve Smith ; Aaron Gilson ; Adam Chrisney ; Adam Michael Clark, PhD ; Amanda Seeff-Charny ; Andrew Scholnick ; Barry Eliot Cole ; Brad Gary ; Brad Maruca ; Brian Munroe ; Burt Rosen ; Carlos Gomez, MD, PhD ; Caroline Moody ; Christy Torkildson ; Claudia Campbell, RN, BSN ; Courtney Snowden ; Dan Cohen ; David Joranson ; David Swankin ; David Woodmansee ; Fritz Bittenbender ; Gail Katz ; Janet McUlsky ; Jason Grove ; Jennifer M. Connelly ; Jerold Roschwalb ; Jim Broatch ; Joel Kurzman ; Jonathan Keyserling ; Joy Buck, RN, PhD ; Joy Buck, RN, PhD ; June Dahl ; Karina Tabor ; Kathryn Tucker ; Kimberley Tiller ; Kristina Lunner ; Lennie Duensing ; Lici Do Canto ; Linda Wase ; Lisa Robin ; Mark Rasmussen ; Mark W. Caverly ; Marsha Stanton, MS, RN ; Mary Bennett ; Michael Splaine ; Michelle Lonchar ; Micke Brown ; Mike Matoon ; Myra Christopher ; Pamela Bennett ; Patricia Barnett ; Paul Arnstein, MD ; Penney Cowan ; Peter Slone ; Rebecca Kirch ; Robert J. Saner ; Robert Twillman, PhD ; Scott Fishman, MD ; Melville, Scott; Stephen Porada ; Steve LaPierre ; Susan Rogers, MS, BSN, RN, CHPN ; Tamara Sloan Anderson ; Tamara Sloan Anderson ; Theresa Doyle ; Wade Delk  
**Cc:** Bonnie Weissfeld  
**Sent:** Tue Feb 24 05:15:39 2009  
**Subject:** RE: REMS Task Force Meeting February 24th

Dear All:

Please find attached a document for review during the proposal development segment of the meeting today.

Regards,  
Steve

Stephen Porada  
American Society of Pain Educators  
6 Erie Street  
Montclair, NJ 07042  
P:973-415-5112  
C: [REDACTED]

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**From:** Will Rowe [mailto:wrowe@painfoundation.org]

**Sent:** Wednesday, February 18, 2009 4:56 PM

**To:** aducca@hdmanet.org; gwt@u.washington.edu; Michna, Edward, M.D.; cmonaco@osteopathic.org; Justine Coffey; judi.buckalew@ppsv.com; Steve Smith; Aaron Gilson; Adam Chrisney; Adam Michael Clark, PhD; Amanda Seeff-Charny; Andrew Scholnick; Barry Eliot Cole; Brad Gary; Brad Maruca; Brian Munroe; Burt Rosen; Carlos Gomez, MD, PhD; Caroline Moody; Christy Torkildson; Claudia Campbell, RN, BSN; Courtney Snowden; Dan Cohen; David Joranson; David Swankin; David Woodmansee; Fritz Bittenbender; Gail Katz; Janet McUlsky; Jason Grove; Jennifer M. Connelly; Jerold Roschwalb; Jim Broatch; Joel Kurzman; Jonathan Keyserling; Joy Buck, RN, PhD; Joy Buck, RN, PhD; June Dahl; Karina Tabor; Kathryn Tucker; Kimberley Tiller; Kristina Lunner; Lennie Duensing; Lici Do Canto; Linda Wase; Lisa Robin; Mark Rasmussen; Mark W. Caverly; Marsha Stanton, MS, RN; Mary Bennett; Michael Splaine; Michelle Lonchar; Micke Brown; Mike Mattoon; Myra Christopher; Pamela Bennett; Patricia Barnett; Paul Arnstein, MD; Penney Cowan; Peter Slone; Rebecca Kirch; Robert J. Saner; Robert Twillman, PhD; Scott Fishman, MD; Scott Melville; Stephen Porada; Steve LaPierre; Susan Rogers, MS, BSN, RN, CHPN; Tamara Sloan Anderson; Tamara Sloan Anderson; Theresa Doyle; Wade Delk

**Cc:** Bonnie Weissfeld

**Subject:** REMS Task Force Meeting February 24th

Dear All:

This is to confirm that there will be a Pain Care Forum REMS Task Force meeting on February 24<sup>th</sup> from 10 a.m. to 4 p.m. in the Conference Room of Powers Pyle Sutter and Verville at 1501 M. St. NW in D.C., Suite 700. For those who are not able to attend in person, the call-in # is: 877 930 8190. Passcode is: 7249303.

**FOR THOSE ATTENDING IN PERSON, PLEASE RSVP TO: BONNIE WEISSFELD, 410 783 7292, EXT 221...**we will be bringing in lunch and want to have an accurate count and we need names for security.

As I mentioned in my previous e-mail, the purpose of the meeting is to create a REMS proposal which we will present to FDA officials when we meet with them. We still do not have a date established for the FDA meeting. I will let you know as soon as I find out.

The Agenda for the February 24<sup>th</sup> Meeting is:

1. Summary of PCF REMS Task Force process
2. Recent information regarding REMS process as stated by the FDA at the February 10<sup>th</sup> meeting
3. Outline of FDAAA statements regarding REMS
4. Discussion of REMS Task Force defined goals and principles
5. Work on the proposal: Creating a proposal that meets our goals, follows our principles, and appears workable with FDA goals
6. Strategy and content for FDA meeting

See you soon.

Will

Will Rowe  
Chief Executive Officer

American Pain Foundation  
201 N. Charles St. Suite 710  
Baltimore, MD 21201

Tel #: 410 783 7292, ext. 225

Cell#: [REDACTED]

[www.painfoundation.org](http://www.painfoundation.org)

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